



FEB 28 2005

Holly D. Kozlowski
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati OH 45202In Re: Patent Term Extension
Application for
U.S. Patent No. 5,444,106

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,444,106, which claims the medical device CeeOn™ Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens - Model 911A, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 956 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 956 days.

Under 35 U.S.C. § 156(c), the period of extension is calculated using the Food and Drug Administration determination of the length of the regulatory review period as published in the Federal Register of July 17, 2002 (67 Fed. Reg. 46989). As so calculated, the period of extension would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,101 - 0) + 493 \\ &= 1,044 \text{ days}\end{aligned}$$

Since the regulatory review period began November 25, 1996, after the patent issued (August 22, 1995), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c).

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,044 days, would extend the patent from August 22, 2012 (35 U.S.C. § 154) to July 1, 2015, which is beyond the 14-year limit (the approval date is April 5, 2001 thus the 14 year limit is April 5, 2015). The period of extension is thus limited to April 5, 2015, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 22, 2012, to and including April 5, 2015, or 956 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

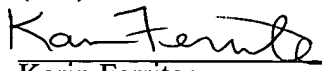
Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,444,106
Granted:	August 22, 1995
Original Expiration Date ¹ :	August 22, 2012
Applicant:	Stephen Q. Zhou, et al.
Owner of Record:	Kabi Pharmacia Ophthalmics, Inc.
Title:	High Refractive Index Silicone Compositions
Classification:	523/107
Product Trade Name:	CeeOn™ Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens - Model 911A
Term Extended:	956 days
Expiration Date:	April 5, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Commissioner for Patents Mail Stop Patent Ext. P.O. Box 1450 Alexandria, VA 22313-1450	By FAX: (571) 273-7744 Attn: Office of Patent Legal Administration
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Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: CeeOn™ Edge Foldable Ultraviolet
Light-Absorbing Posterior Chamber
Intraocular Lens - Model 911A
FDA Docket No. : 01E-0404

¹Subject to the provisions of 35 U.S.C. § 41(b).